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Display Date 11-17-04 @ 1:52p
Publication Date 11-19-04
Certifier D. Hawkins

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0229]

Guidance for Industry on Continuous Marketing Applications: Pilot 2—Scientific Feedback and Interactions During Development of Fast Track Products Under the Prescription Drug User Fee Act of 1992; Extension of Application Deadline

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of extension of application deadline.

SUMMARY: The Food and Drug Administration (FDA) is announcing an extension for acceptance of applications to its continuous marketing applications (CMA) Pilot 2 program implemented under the guidance for industry entitled "Continuous Marketing Applications: Pilot 2–Scientific Feedback and Interactions During Development of Fast Track Products Under PDUFA." The extension applies only to the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) review divisions that have not received acceptable applications for participation in the Pilot 2 program.

DATES: Submit written or electronic comments on agency guidances at any time. FDA will accept applications through December 31, 2004, for participation in the CMA Pilot 2 program per the restrictions described in the **SUMMARY** section of this document.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and

Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communications, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist either office in processing your request. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT:

John Jenkins, Center for Drug Evaluation and Research (HFD–020), Food and Drug Administration, 5515 Security Lane, Rockville, MD 20852, 301–594–3937, or

Robert A. Yetter, Center for Biologics Evaluation and Research (HFM–25), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0373.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 6, 2003 (68 FR 57696), FDA announced the availability of a guidance entitled "Continuous Marketing Applications: Pilot 2–Scientific Feedback and Interactions During Development of Fast Track Products Under PDUFA." This guidance is one in a series of guidance documents that FDA agreed to draft and implement in conjunction with the June 2002 reauthorization of the Prescription Drug User Fee Act of 1992 (PDUFA). The guidance discusses how the agency will implement a CMA Pilot

2 program for frequent scientific feedback and interactions between FDA and applicants during the investigational phase of development for certain Fast Track drug and biological products.

Under the CMA Pilot 2 program, certain drug and biologic products that have been designated as Fast Track (i.e., products intended to treat a serious and/or life-threatening disease for which there is an unmet medical need) are eligible to be considered for participation in the CMA Pilot 2 program. The CMA Pilot 2 program is an exploratory program, and FDA will evaluate its impact on the investigational phase of drug development. Under the pilot program, a maximum of one Fast Track product per review division in CDER and CBER will be selected to participate. The guidance provides information regarding the selection of applications for the CMA Pilot 2 program, the formation of agreements between FDA and applicants on the investigational new drug (IND) communication process, and other procedural aspects of the CMA Pilot 2 program.

Per section III.A.4 of the guidance, applicants were originally asked to apply for participation in the CMA Pilot 2 program from October 6, 2003, through December 8, 2003. For review divisions that had not received any acceptable CMA Pilot 2 program applications by December 8, 2003, applications were also accepted between February 9, 2004, and September 30, 2004. This notice further extends that deadline to December 31, 2004, to ensure inclusive and relevant results from the CMA Pilot 2 program. A description of the application submission process, evaluation criteria, and selection process is in the guidance. Applications will be accepted only in CDER and CBER divisions that have not previously selected a Pilot 2 application. Information regarding the CDER and CBER divisions that are available to select

the CMA Pilot 2 program application can be found on FDA's Web site at *http://www.fda.gov/cder/pdufa/CMA.htm*. For each of these divisions, the first application received that adequately meets the evaluation criteria will be accepted into the CMA Pilot 2 program and applicants will be informed within 6 weeks of application submission.

II. Electronic Access

Persons with access to the Internet can obtain the guidance at *http://www.fda.gov/cder/guidance/index.htm* or at *http://www.fda.gov/cber/guidelines.htm.*

Dated: 11/15/04
November 15, 2004.

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 04–????? Filed ??–??–04; 8:45 am]

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